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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6004

January 16, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Francisco Gil, President
Imperial Drug & Spice Corp.
5620 Kennedy Blvd.
West New York, New Jersey 07093

FILE NO.: 02-NWJ-16

Dear Mr. Gil:

From November 28 through December 5, 2001, the U.S Food and Drug Administration conducted an inspection of your facility located at 5620 Kennedy Blvd., West New York, New Jersey. During the inspection our investigators documented significant deviations from the Current Good Manufacturing Practices Regulations (cGMPs) Title 21, Code of Federal Regulations, Part 210 and 211, in conjunction with your firm's manufacture of over-the-counter (OTC) drug products.

The inspection revealed that drug products manufactured at your facility are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform with cGMPs, to assure that such drug products meet the requirements of the Act. The deviations were presented to you on a FDA-483, List of Inspectional Observations, at the close of the inspection on December 5, 2001.

The significant observations are as follows:

1. No assurance of the identity or purity for the following raw materials that your firm repackages: Boric Acid, NF powder, Sodium Bicarbonate, USP powder, and Castor Oil, USP. Your firm fails to perform any identity testing and has no acceptance specifications for the above referenced raw materials.

2. Your firm has no system in place to trace the use of the raw materials: Boric Acid, NF powder, Sodium Bicarbonate, USP powder, and Castor Oil, USP, from receipt through distribution.

3. Your firm has no batch records for the repackaging of the OTC drug products: Boric Acid Powder, Bicarbonato De Soda, and Aceite De Ricino.

4. Your firm has no stability data for the OTC drug products: Boric Acid Powder, Bicarbonato De Soda, and Aceite De Ricino.

5. Failure to maintain retain samples for all batches of finished drug products repackaged and distributed by your firm.

6. Your firm's label controls are inadequate. For example, Boric Acid Powder, lot #103107 and Bicarbonato de Sodium, lot #111901 were released without an expiration date on the labels.

7. No cGMP training for your firm's employees who are responsible for the repackaging and release of OTC drug products.

8. No written procedures for the following areas: Responsibilities of the Quality Control Unit, Receiving, Repackaging, Label Issuance and Reconciliation, Recalls, Complaint Handling, and Distribution.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practices Regulations. We recommend you conduct a comprehensive evaluation of your facility to determine cGMP compliance. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter. Your response should include specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,

Edward H. Wilkens, for
Douglas I. Ellsworth
District Director
New Jersey District Office

AC:slm